

118TH CONGRESS
1ST SESSION

H. R. 1418

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs and generic new animal drugs.

IN THE HOUSE OF REPRESENTATIVES

MARCH 7, 2023

Mr. PENCE (for himself and Ms. SCHRIER) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs and generic new animal drugs.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Animal Drug User Fee
5 Amendments of 2023”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents for this Act is the following:

Sec. 1. Short title.

Sec. 2. Table of contents.

TITLE I—FEES RELATING TO ANIMAL DRUGS

Sec. 101. Short title; finding.

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TITLE II—FEES RELATING TO GENERIC ANIMAL DRUGS

Sec. 201. Short title; finding.
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1 **TITLE I—FEES RELATING TO** 2 **ANIMAL DRUGS**

3 **SEC. 101. SHORT TITLE; FINDING.**

4 (a) **SHORT TITLE.**—This title may be cited as the
 5 “Animal Drug User Fee Amendments of 2023”.

6 (b) **FINDING.**—Congress finds that the fees author-
 7 ized by the amendments made in this title will be dedi-
 8 cated toward expediting the animal drug development
 9 process and the review of new and supplemental animal
 10 drug applications and investigational animal drug submis-
 11 sions as set forth in the goals identified for purposes of
 12 part 4 of subchapter C of chapter VII of the Federal Food,
 13 Drug, and Cosmetic Act, in the letters from the Secretary
 14 of Health and Human Services to the Chairman of the
 15 Committee on Energy and Commerce of the House of
 16 Representatives and the Chairman of the Committee on
 17 Health, Education, Labor, and Pensions of the Senate as
 18 set forth in the Congressional Record.

1 **SEC. 102. DEFINITIONS.**

2 Section 739(8)(I) of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 379j–11(8)(I)) is amended to
4 read as follows:

5 “(I) The activities necessary for implemen-
6 tation of the United States and European
7 Union Mutual Recognition Agreement for Phar-
8 maceutical Good Manufacturing Practice In-
9 spections, and the United States and United
10 Kingdom Recognition Agreement Sectoral
11 Annex for Pharmaceutical Good Manufacturing
12 Practices, and future mutual recognition agree-
13 ments, with respect to animal drug products
14 subject to review, including implementation ac-
15 tivities prior to and following product ap-
16 proval.”.

17 **SEC. 103. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**
18 **FEES.**

19 (a) TYPES OF FEES.—Section 740(a)(1)(A)(ii) of the
20 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
21 12(a)(1)(A)(ii)) is amended—

22 (1) in subclause (I), by striking “and” at the
23 end;

24 (2) in subclause (II), by striking the period at
25 the end and inserting “; and”; and

26 (3) by adding at the end the following:

1 “(III) an application for condi-
2 tional approval under section 571 of a
3 new animal drug for which an animal
4 drug application submitted under sec-
5 tion 512(b)(1) has been previously ap-
6 proved under section 512(d)(1) for
7 another intended use.”.

8 (b) FEE REVENUE AMOUNTS.—Section 740(b)(1) of
9 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 379j–12(b)(1)) is amended to read as follows:

11 “(1) IN GENERAL.—Subject to subsections (c),
12 (d), (f), and (g), for each of fiscal years 2024
13 through 2028, the fees required under subsection (a)
14 shall be established to generate a total revenue
15 amount of \$33,500,000.”.

16 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—

17 (1) ANNUAL FEE SETTING.—Section 740(c)(1)
18 of the Federal Food, Drug, and Cosmetic Act (21
19 U.S.C. 379j–12(c)(1)) is amended to read as follows:

20 “(1) ANNUAL FEE SETTING.—Not later than
21 60 days before the start of each fiscal year begin-
22 ning after September 30, 2023, the Secretary
23 shall—

24 “(A) establish for that fiscal year animal
25 drug application fees, supplemental animal drug

1 application fees, animal drug sponsor fees, ani-
2 mal drug establishment fees, and animal drug
3 product fees based on the revenue amounts es-
4 tablished under subsection (b) and the adjust-
5 ments provided under this subsection; and

6 “(B) publish such fee revenue amounts
7 and fees in the Federal Register.”.

8 (2) INFLATION ADJUSTMENT.—Section
9 740(c)(2) of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 379j–12(c)(2)) is amended—

11 (A) in subparagraph (A)—

12 (i) in the matter preceding clause (i),
13 by striking “2020” and inserting “2025”;
14 and

15 (ii) in clause (iii), by striking “Balti-
16 more” and inserting “Arlington-Alexan-
17 dria”; and

18 (B) in subparagraph (B), by striking
19 “2020” and inserting “2025”.

20 (3) WORKLOAD ADJUSTMENTS.—Paragraph (3)
21 of section 740(c) of the Federal Food, Drug, and
22 Cosmetic Act (21 U.S.C. 379j–12(c)) is amended—

23 (A) in subparagraph (A)—

24 (i) in the matter preceding clause

25 (i)—

1 (I) by striking “2020” and in-
2 sserting “2025”; and

3 (II) by striking “subparagraphs
4 (B) and (C)” and inserting “subpara-
5 graph (B)”;

6 (ii) in clause (i) by striking “and” at
7 the end; and

8 (iii) by striking clause (ii) and insert-
9 ing the following:

10 “(ii) such adjustment shall be made
11 for each fiscal year that the adjustment de-
12 termined by the Secretary is greater than
13 3 percent, except for the first fiscal year
14 that the adjustment is greater than 3 per-
15 cent; and

16 “(iii) the Secretary shall publish in
17 the Federal Register notice under para-
18 graph (1) the amount of such adjustment
19 and the supporting methodologies.”;

20 (B) by striking subparagraph (B); and

21 (C) by redesignating subparagraph (C) as
22 subparagraph (B).

23 (4) FINAL YEAR ADJUSTMENT.—Section
24 740(c)(4) of the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 379j-12(c)(4)) is amended to read
2 as follows:

3 “(4) OPERATING RESERVE ADJUSTMENT.—

4 “(A) IN GENERAL.—For fiscal year 2025
5 and each subsequent fiscal year, after the fee
6 revenue amount established under subsection
7 (b) is adjusted in accordance with paragraphs
8 (2) and (3), the Secretary shall—

9 “(i) increase the fee revenue amount
10 for such fiscal year, if necessary to provide
11 an operating reserve of not less than 12
12 weeks; or

13 “(ii) if the Secretary has an operating
14 reserve in excess of the number of weeks
15 specified in subparagraph (C) for that fis-
16 cal year, the Secretary shall decrease the
17 fee revenue amount to provide not more
18 than the number of weeks specified in sub-
19 paragraph (C) for that fiscal year.

20 “(B) CARRYOVER USER FEES.—For pur-
21 poses of this paragraph, the operating reserve
22 of carryover user fees for the process for the re-
23 view of animal drug applications does not in-
24 clude carryover user fees that have not been ap-
25 propriated.

1 “(C) NUMBER OF WEEKS OF OPERATING
2 RESERVES.—The number of weeks of operating
3 reserves specified in this subparagraph is—

4 “(i) 22 weeks for fiscal year 2025;

5 “(ii) 20 weeks for fiscal year 2026;

6 “(iii) 18 weeks for fiscal year 2027;

7 and

8 “(iv) 16 weeks for fiscal year 2028.

9 “(D) PUBLICATION.—If an adjustment to
10 the operating reserve is made under this para-
11 graph, the Secretary shall publish in the Fed-
12 eral Register notice under paragraph (1) the ra-
13 tionale for the amount of the adjustment and
14 the supporting methodologies.”.

15 (d) EXEMPTION FROM FEES.—Section 740(d)(4) of
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 379j–12(d)(4)) is amended to read as follows:

18 “(4) EXEMPTION FROM FEES FOR CERTAIN
19 ANIMAL DRUG APPLICATIONS.—Fees under para-
20 graphs (2), (3), and (4) of subsection (a) shall not
21 apply with respect to any person who is the named
22 applicant or sponsor of an animal drug application,
23 supplemental animal drug application, or investiga-
24 tional animal drug submission if such application or
25 submission involves the intentional genomic alter-

1 ation of an animal that is intended to produce a
2 drug, device, or biological product subject to fees
3 under section 736, 738, 744B, or 744H.”.

4 (e) CREDITING AND AVAILABILITY OF FEES.—

5 (1) AUTHORIZATION OF APPROPRIATIONS.—

6 Section 740(g)(3) of the Federal Food, Drug, and
7 Cosmetic Act (21 U.S.C. 379j–12(g)(3)) is amended
8 by striking “2019 through 2023” and inserting
9 “2024 through 2028”.

10 (2) COLLECTION SHORTFALLS.—Section 740(g)
11 of the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 379j–12(g)) is amended—

13 (A) in paragraph (3), by striking “and
14 paragraph (5)”;

15 (B) by striking paragraph (5).

16 **SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENTS.**

17 Section 740A of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 379j–13) is amended—

19 (1) in subsection (a), by striking “2018” and
20 inserting “2023”;

21 (2) by striking “2019” each place it appears in
22 subsections (a) and (b) and inserting “2024”; and

23 (3) in subsection (d)—

24 (A) in paragraph (1), by striking “2023”
25 and inserting “2028”; and

1 (B) in paragraph (5), by striking “2023”
2 and inserting “2028”.

3 **SEC. 105. SAVINGS CLAUSE.**

4 Notwithstanding the amendments made by this title,
5 part 4 of subchapter C of chapter VII of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 379j–11 et seq.), as
7 in effect on the day before the date of enactment of this
8 title, shall continue to be in effect with respect to animal
9 drug applications and supplemental animal drug applica-
10 tions (as defined in such part as of such day) that on or
11 after October 1, 2018, but before October 1, 2023, were
12 accepted by the Food and Drug Administration for filing
13 with respect to assessing and collecting any fee required
14 by such part for a fiscal year prior to fiscal year 2024.

15 **SEC. 106. EFFECTIVE DATE.**

16 The amendments made by this title shall take effect
17 on October 1, 2023, or the date of the enactment of this
18 Act, whichever is later, except that fees under part 4 of
19 subchapter C of chapter VII of the Federal Food, Drug,
20 and Cosmetic Act, as amended by this title, shall be as-
21 sessed for animal drug applications and supplemental ani-
22 mal drug applications received on or after October 1,
23 2023, regardless of the date of the enactment of this Act.

1 **SEC. 107. SUNSET DATES.**

2 (a) **AUTHORIZATION.**—Sections 739 and 740 of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
4 12) shall cease to be effective October 1, 2028.

5 (b) **REPORTING REQUIREMENTS.**—Section 740A of
6 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 379j–13) shall cease to be effective January 31, 2029.

8 (c) **PREVIOUS SUNSET PROVISION.**—Effective Octo-
9 ber 1, 2023, subsections (a) and (b) of section 107 of the
10 Animal Drug User Fee Amendments of 2018 (Public Law
11 115–234) are repealed.

12 **TITLE II—FEES RELATING TO**
13 **GENERIC ANIMAL DRUGS**

14 **SEC. 201. SHORT TITLE; FINDING.**

15 (a) **SHORT TITLE.**—This title may be cited as the
16 “Animal Generic Drug User Fee Amendments of 2023”.

17 (b) **FINDING.**—Congress finds that the fees author-
18 ized by the amendments made in this title will be dedi-
19 cated toward expediting the generic new animal drug de-
20 velopment process and the review of abbreviated applica-
21 tions for generic new animal drugs, supplemental abbrevi-
22 ated applications for generic new animal drugs, and in-
23 vestigational submissions for generic new animal drugs as
24 set forth in the goals identified for purposes of part 5 of
25 subchapter C of chapter VII of the Federal Food, Drug,
26 and Cosmetic Act, in the letters from the Secretary of

1 Health and Human Services to the Chairman of the Com-
2 mittee on Energy and Commerce of the House of Rep-
3 resentatives and the Chairman of the Committee on
4 Health, Education, Labor and Pensions of the Senate as
5 set forth in the Congressional Record.

6 **SEC. 202. AUTHORITY TO ASSESS AND USE GENERIC NEW**
7 **ANIMAL DRUG FEES.**

8 (a) TYPES OF FEES.—Section 741(a) of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21(a)) is
10 amended by adding at the end the following:

11 “(4) GENERIC INVESTIGATIONAL NEW ANIMAL
12 DRUG FILE FEE.—

13 “(A) IN GENERAL.—

14 “(i) ASSESSMENT OF FEE.—Each per-
15 son that submits a request to establish a
16 generic investigational new animal drug
17 file on or after October 1, 2023, shall be
18 assessed a fee as established under sub-
19 section (c).

20 “(ii) EXISTING FILES.—In the case of
21 a generic investigational new animal drug
22 file established prior to October 1, 2023,
23 each person that makes a submission to
24 such a file on or after October 1, 2023,
25 shall be assessed a fee for the first submis-

1 sion on or after October 1, 2023, as estab-
2 lished under subsection (c).

3 “(B) PAYMENT.—The fee required by sub-
4 paragraph (A)(i) shall be due upon submission
5 of the request to establish the generic investiga-
6 tional new animal drug file. The fee required by
7 subparagraph (A)(ii) shall be due upon the first
8 submission to the generic investigational new
9 animal drug file.

10 “(C) EXCEPTIONS.—

11 “(i) TERMINATION.—If a person
12 makes a submission to the generic inves-
13 tigational new animal drug file to termi-
14 nate that file, the person shall not be sub-
15 ject to a fee under subparagraph (A)(ii)
16 for that submission.

17 “(ii) TRANSFERS.—If a person makes
18 a submission to the generic investigational
19 new animal drug file to transfer that file
20 to a different generic new animal drug
21 sponsor, the person shall not be subject to
22 a fee under subparagraph (A)(ii) for that
23 submission.”.

1 (b) FEE REVENUE AMOUNTS.—Section 741(b) of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
3 21(b)) is amended—

4 (1) in paragraph (1)—

5 (A) by striking “2019 through 2023” and
6 inserting “2024 through 2028”; and

7 (B) by striking “\$18,336,340” and insert-
8 ing “\$25,000,000”; and

9 (2) in paragraph (2)—

10 (A) in subparagraph (A)—

11 (i) by striking “25 percent” and in-
12 serting “20 percent”; and

13 (ii) by inserting before the semicolon
14 at the end the following: “and subsection
15 (a)(4) (relating to generic investigational
16 new animal drug files)”;

17 (B) in subparagraph (B), by striking “37.5
18 percent” and inserting “40 percent”; and

19 (C) in subparagraph (C), by striking “37.5
20 percent” and inserting “40 percent”.

21 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—

22 (1) ANNUAL FEE SETTING.— Section 741(c)(1)
23 of the Federal Food, Drug, and Cosmetic Act (21
24 U.S.C. 379j–21(c)(1)) is amended to read as follows:

1 “(1) ANNUAL FEE SETTING.—The Secretary
2 shall establish, not later than 60 days before the
3 start of each fiscal year beginning after September
4 30, 2023, for that fiscal year—

5 “(A) abbreviated application fees that are
6 based on the revenue amounts established
7 under subsection (b), the adjustments provided
8 under this subsection, and the amount of fees
9 anticipated to be collected under subsection
10 (a)(4) during that fiscal year;

11 “(B) generic new animal drug sponsor
12 fees, and generic new animal drug product fees,
13 based on the revenue amounts established
14 under subsection (b) and the adjustments pro-
15 vided under this subsection; and

16 “(C) a generic investigation new animal
17 drug file fee of \$50,000 for each request or
18 submission covered by subsection (a)(4)(A).”.

19 (2) INFLATION ADJUSTMENT.—Section
20 741(c)(2) of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 379j–21(c)(2)) is amended—

22 (A) in subparagraph (A)—

23 (i) in the matter preceding clause (i),
24 by striking “2020” and inserting “2025”;
25 and

1 (ii) in clause (iii), by striking “Balti-
2 more” and inserting “Arlington-Alexan-
3 dria”; and

4 (B) in subparagraph (B), by striking
5 “2020” and inserting “2025”.

6 (3) WORKLOAD ADJUSTMENT.—Section
7 741(c)(3) of the Federal Food, Drug, and Cosmetic
8 Act (21 U.S.C. 379j–21(c)(3)) is amended—

9 (A) in subparagraph (A)—

10 (i) in the matter preceding clause (i),
11 by striking “2020” and inserting “2025”;

12 (ii) in clause (i)—

13 (I) by striking “and investiga-
14 tional generic new animal drug pro-
15 tocol submissions” and inserting “in-
16 vestigational generic new animal drug
17 protocol submissions, requests to es-
18 tablish a generic investigational new
19 animal drug file, and generic inves-
20 tigational new animal drug meeting
21 requests”; and

22 (II) by striking “; and” and in-
23 serting a semicolon;

24 (iii) by redesignating clause (ii) as
25 clause (iii); and

1 (iv) by inserting after clause (i) the
2 following:

3 “(ii) if the workload adjustment cal-
4 culated by the Secretary for the adjust-
5 ment in clause (i) exceeds 25 percent, the
6 Secretary shall use 25 percent for the ad-
7 justment; and”; and

8 (B) in subparagraph (B), by striking
9 “2021 through 2023” and inserting “2026
10 through 2028”.

11 (4) FINAL YEAR ADJUSTMENT.—Section
12 741(c)(4) of the Federal Food, Drug, and Cosmetic
13 Act (21 U.S.C. 379j–21(c)(4)) is amended—

14 (A) striking “2023” each place it appears
15 and inserting “2028”; and

16 (B) striking “2024” and inserting “2029”.

17 (d) FEE WAIVER OR REDUCTION; EXEMPTION FROM
18 FEES.—Subsection (d) of section 741 of the Federal
19 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21) is
20 amended to read as follows:

21 “(d) FEE WAIVER OR REDUCTION.—The Secretary
22 shall grant a waiver from, or a reduction of, one or more
23 fees assessed under subsection (a) where the Secretary
24 finds that the generic new animal drug is intended solely
25 to provide for a minor use or minor species indication.”.

1 (e) EFFECT OF FAILURE TO PAY FEES.—Section
2 741(e) of the Federal Food, Drug, and Cosmetic Act (21
3 U.S.C. 379j–21(e)) is amended by striking “The Secretary
4 may discontinue” and inserting “A request to establish a
5 generic investigational new animal drug file that is sub-
6 mitted by a person subject to fees under subsection (a)
7 shall be considered incomplete and shall not be accepted
8 for action by the Secretary until all fees owed by such per-
9 son have been paid. The Secretary may discontinue”.

10 (f) ASSESSMENT OF FEES.—Section 741(f)(2) of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
12 21(f)(2)) is amended by striking “sponsors, and generic
13 new animal drug products at any time” and inserting
14 “products, generic new animal drug sponsors, and generic
15 investigational new animal drug files at any time”.

16 (g) CREDITING AND AVAILABILITY OF FEES.—Sec-
17 tion 741(g) of the Federal Food, Drug, and Cosmetic Act
18 (21 U.S.C. 379j–21(g)) is amended—

19 (1) in paragraph (3), by striking “2019
20 through 2023” and inserting “2024 through 2028”;

21 (2) by striking the following:

22 “(4) OFFSET.—If the sum of the cumulative
23 amount of fees collected under this section for the
24 fiscal years 2014 through 2016 and the amount of
25 fees estimated to be collected under this section for

1 fiscal year 2017 exceeds the cumulative amount ap-
2 propriated under paragraph (3) for the fiscal years
3 2014 through 2017, the excess amount shall be
4 credited to the appropriation account of the Food
5 and Drug Administration as provided in paragraph
6 (1), and shall be subtracted from the amount of fees
7 that would otherwise be authorized to be collected
8 under this section pursuant to appropriation Acts
9 for fiscal year 2018.”; and

10 (3) by adding at the end the following:

11 “(5) RECOVERY OF COLLECTION SHORT-
12 FALLS.—The amount of fees otherwise authorized to
13 be collected under this section shall be increased—

14 “(A) for fiscal year 2026, by the amount,
15 if any, by which the amount collected under this
16 section and appropriated for fiscal year 2024
17 falls below the amount of fees authorized for
18 fiscal year 2024 under paragraph (3);

19 “(B) for fiscal year 2027, by the amount,
20 if any, by which the amount collected under this
21 section and appropriated for fiscal year 2025
22 falls below the amount of fees authorized for
23 fiscal year 2025 under paragraph (3); and

24 “(C) for fiscal year 2028, by the amount,
25 if any, by which the amount collected under this

1 section and appropriated for fiscal years 2026
2 and 2027 (including estimated collections for
3 fiscal year 2027) falls below the amount of fees
4 authorized for such fiscal years under para-
5 graph (3).”.

6 (h) DEFINITIONS.—Section 741(k) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21(k)) is
8 amended—

9 (1) by redesignating paragraphs (8), (9), (10),
10 and (11) as paragraphs (9), (10), (11), and (13), re-
11 spectively;

12 (2) by inserting after paragraph (7) the fol-
13 lowing:

14 “(8) GENERIC INVESTIGATIONAL NEW ANIMAL
15 DRUG MEETING REQUEST.—The term ‘generic inves-
16 tigational new animal drug meeting request’ means
17 a request submitted by a generic new animal drug
18 sponsor to meet with the Secretary to discuss an in-
19 vestigational submission for a generic new animal
20 drug.”;

21 (3) in paragraph (11) (as so redesignated), by
22 adding at the end the following:

23 “(I) The activities necessary for explo-
24 ration and implementation of the United States
25 and European Union Mutual Recognition

1 Agreement for Pharmaceutical Good Manufac-
2 turing Practice Inspections, and the United
3 States and United Kingdom Recognition Agree-
4 ment Sectoral Annex for Pharmaceutical Good
5 Manufacturing Practices, and future mutual
6 recognition agreements, with respect to generic
7 new animal drug products subject to review, in-
8 cluding implementation activities prior to and
9 following product approval.”; and

10 (4) by inserting after paragraph (11) (as so re-
11 designated) the following:

12 “(12) REQUEST TO ESTABLISH A GENERIC IN-
13 VESTIGATIONAL NEW ANIMAL DRUG FILE.—The
14 term ‘request to establish a generic investigational
15 new animal drug file’ means the submission to the
16 Secretary of a request to establish a generic inves-
17 tigational new animal drug file to contain investiga-
18 tional submissions for a generic new animal drug.”.

19 **SEC. 203. REAUTHORIZATION; REPORTING REQUIREMENTS.**

20 Section 742 of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 379j–22) is amended—

22 (1) in subsection (a), by striking “2018” and
23 inserting “2023”;

24 (2) by striking “2019” each place it appears in
25 subsections (a) and (b) and inserting “2024”; and

1 (3) in subsection (d), by striking “2023” each
2 place it appears and inserting “2028”.

3 **SEC. 204. SAVINGS CLAUSE.**

4 Notwithstanding the amendments made by this title,
5 part 5 of subchapter C of chapter VII of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 379j–21 et seq.), as
7 in effect on the day before the date of enactment of this
8 title, shall continue to be in effect with respect to abbrevi-
9 ated applications for a generic new animal drug and sup-
10 plemental abbreviated applications for a generic new ani-
11 mal drug (as defined in such part as of such day) that
12 on or after October 1, 2018, but before October 1, 2023,
13 were accepted by the Food and Drug Administration for
14 filing with respect to assessing and collecting any fee re-
15 quired by such part for a fiscal year prior to fiscal year
16 2024.

17 **SEC. 205. EFFECTIVE DATE.**

18 The amendments made by this title shall take effect
19 on October 1, 2023, or the date of the enactment of this
20 Act, whichever is later, except that fees under part 5 of
21 subchapter C of chapter VII of the Federal Food, Drug,
22 and Cosmetic Act, as amended by this title, shall be as-
23 sessed for abbreviated applications for a generic new ani-
24 mal drug and supplemental abbreviated applications for

1 a generic new animal drug received on or after October
2 1, 2023, regardless of the date of enactment of this Act.

3 **SEC. 206. SUNSET DATES.**

4 (a) **AUTHORIZATION.**—Section 741 of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21) shall
6 cease to be effective October 1, 2028.

7 (b) **REPORTING REQUIREMENTS.**—Section 742 of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
9 22) shall cease to be effective January 31, 2029.

10 (c) **PREVIOUS SUNSET PROVISION.**—Effective Octo-
11 ber 1, 2023, subsections (a) and (b) of section 206 of the
12 Animal Generic Drug User Fee Amendments of 2018
13 (Public Law 115–234) are repealed.

○